

Risk Assessment of Bioaccumulative Substances Part II: Description of a Model Framework

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Holistic Integrated Tiered Risk Assessment

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Summary

This report provides a proposal for a framework for risk assessment of bioaccumulative substances, either from produced water discharges or present as background contamination. The proposed framework is such that it is compatible to the current EIF risk assessment models that are used in the Norwegian offshore oil and gas industry. The risk assessment approach selected for this framework is based on the use of critical body residues (CBR); i.e., body-tissue concentrations above which adverse effects are expected. A three-tiered risk assessment approach is distinguished: tier 1 for worst-case screening purposes; tier 2 based on probabilistic risk assessment using species sensitivity distributions and tier 3 focussing on population modelling for specific species. The latter tier is, because of its specific characteristics, not elaborated in detail.

It is proposed to use a food-chain accumulation model to translate species sensitivity thresholds on the basis of CBR into external threshold concentrations, those external thresholds could then be used to either derive an ecosystem PNEC (tier I) or Species Sensitivity Distribution (tier II). This would provide a pragmatic approach to risk assessment of bioaccumulative substances in the context of the EIF modelling framework.

Finally, an outline is provided for a research project in which the a risk assessment model for bioaccumulative substances is developed. This model will then be applied to two cases for purposes of demonstration and evaluation. An indication of workload and planning is provided.

1 Introduction

1.1 Background

The interest in oil and gas reserves in the Arctic region is increasing. However, operating in icy conditions and coldness includes technical challenges and special concerns to HSE (Health Safety and Environment) issues. Arctic environments are considered to be sensitive to physical and chemical stress [1].

Before activities in such areas can be developed, environmental risks need to be assessed. Risk assessment in the Arctic is not straightforward. As Arctic species have some specific characteristics like antifreeze systems, highly variable body-fat contents and low development times it is not known how sensitive Arctic species are compared to temperate species. Furthermore, the persistence and lipophilicity of some pollutants (either discharged by oil and gas industry or resulting from long-range transport) allows them to accumulate in animals and transport through the food-web, becoming more concentrated in top predators. Those background contaminants entering the Arctic by long-range transport might already pose a risk to Arctic species.

Tools for environmental assessment, presently available, relate environmental risk to ambient environmental concentrations (water, sediment). The risk of bioaccumulating pollutants does, however, not only directly descend from concentrations in water and sediment; exposure through the food-web is also relevant. Persistent bioaccumulative substances are not included in most current risk assessment tools. StatoilHydro recognised these issues and initiated a programme, called “Tuning existing environmental risk assessment tools to the Arctic environment”, in order to properly evaluate the potential for impacts of activities in the Arctic.

The present study focuses on the development of a (chemical) risk assessment model for the Arctic that is capable of dealing with bioaccumulative substances. It integrates bioaccumulation models with risk models. Currently, the Dutch institute of Ecology Research (NIOO) is developing a model including principles from the OMEGA model (Nijmegen University, [2, 3]) to model bioaccumulation in the (Arctic) food-web. This model can potentially be used as a basis for risk assessment of bioaccumulating substances in the Arctic environment. To investigate whether this model can serve as a basis for environmental risk assessment, a feasibility/concept development study on how to derive and define risk estimates from internal concentrations was initiated and reported in the current document.

1.2 Aim and Scope

The aim of this study was to define a concept for environmental risk assessment of bioaccumulating substances and to identify studies required to develop this concept. This study consisted of the following main tasks:

1. Description of the aim and requirements of the intended risk model;
2. Identification and analyses of available methods to calculate risk from internal concentrations;
3. Defining the conceptual risk model;
4. Gap analysis and development of a research proposal.

A main requirement of the model that will be developed for bioaccumulating substances is that the risk assessment endpoints should be compatible with the risk endpoints of models for non-bioaccumulating toxicants

(e.g. risk-characterisation-ratio, fraction species affected). This should allow for a comparison of risks from bioaccumulating and non- bioaccumulating substances.

1.3 Reading guide

In chapter 2 we provide the background for risk assessment of bioaccumulative substances. This is a summary of a more detailed literature study reported separately [4], In chapter 3 a proposed modelling concept for a two tiered risk assessment is provided. Chapter 4 provides an outline of a research project with the objective to develop the proposed risk assessment model, including an estimate of the required workload and related budget and planning.

2 Environmental risk assessment of bioaccumulative substances

2.1 Introduction

The generic approach to environmental risk assessment is based on a comparison of exposure and ecosystem sensitivity (effect levels). For non bioaccumulating substances (often defined as substances with a log octanol water partitioning coefficient ($\log K_{ow}$) <3) environmental risk is directly related to external concentrations, while for bioaccumulating substances risk is merely related to internal concentrations in body tissues of target species. This complicates the generic approach to risk assessment for bioaccumulating chemicals, as the process of bioaccumulation should also be taken into account.

In risk assessment for bioaccumulating substances four main steps can be distinguished:

1. Exposure modelling (from discharge to exposure concentrations);
2. Bioaccumulation modelling (from exposure to internal concentrations);
3. Effect assessment (from internal concentrations to effects);
4. Risk assessment (from effects to environmental risk).

The first main step (exposure modelling) is not different than for non-bioaccumulating chemicals, except for the fact that resulting environmental concentrations are often very low and hardly measurable if not immeasurable. The three subsequent steps will be discussed in the following paragraphs.

2.2 From exposure to internal concentrations

2.2.1 Principles of bioaccumulation modelling

The term bioaccumulation can be used in a general sense to describe situations where organisms acquire higher concentrations of certain contaminants in their body than are present in their food and/or the ambient medium in which they live. Bioaccumulation is the result of both bioconcentration and biomagnification, where bioconcentration is the internal concentration as a result of waterborne exposures, while biomagnification is the result of exposure to the contaminant through the food (prey organisms). Organisms may take up contaminants from water or from contaminated food and can eliminate contaminants by excretion or metabolism. If the uptake is higher than the elimination, elevated levels of contaminants occur within the organism. Uptake and elimination processes vary between species and substances. Most a-polar, organic substances (e.g. naphthalene and other PAHs (Polycyclic Aromatic Hydrocarbons)) are hydrophobic (poorly soluble in water) and (therefore) lipophilic. While the concentrations of these contaminants dissolved in water are very low, the concentrations in aquatic organisms can be high. This is because accumulation of these compounds in the lipid rich tissues of organisms takes place as a result of equilibrium partitioning between water and lipids. The study of Smitková et al. [5] shows the importance of the lipid content of fish for accumulation of chemicals. In fat fish (20% lipid content), concentration factors are higher than in fish with 5% lipid content. The authors conclude that incorporation of lipid content improves exposure assessment for human and ecological risks substantially.

total or nominal concentration

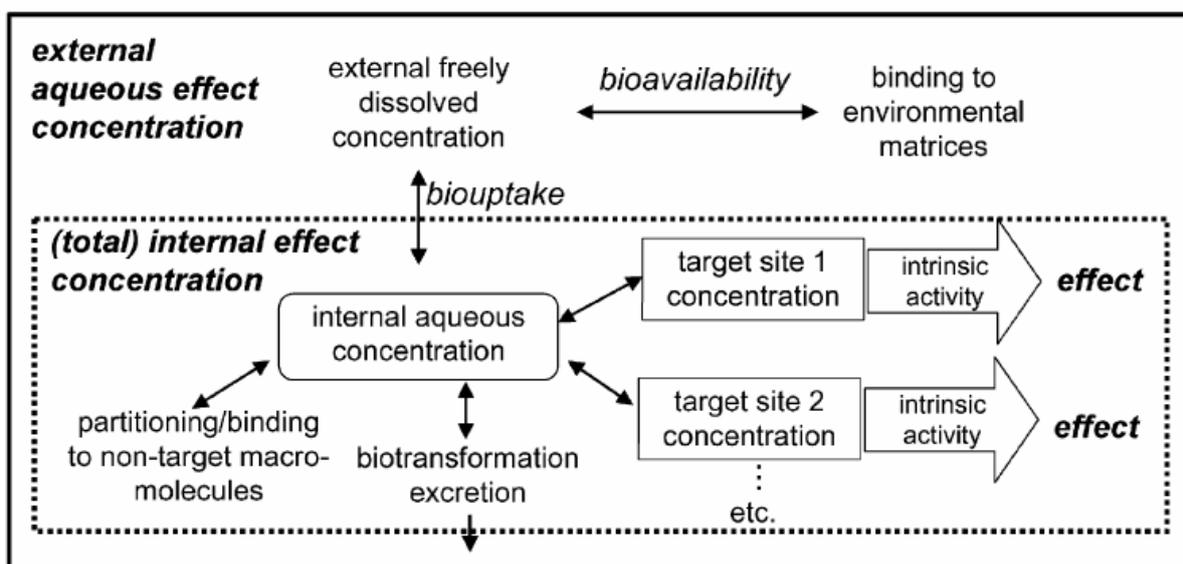


Figure 1 Relationship between total, external, and internal effect concentrations and distribution to different target sites [6].

The potential for bioaccumulation is often expressed as the bioconcentration factor (BCF) or the bioaccumulation factor (BAF), based on the ratio of tissue concentration vs. water concentration. Besides BCF and BAF, biomagnification factors (BMF) can be used to quantify the bioaccumulation potential.

The BMF is defined as the relative concentration in a predatory animal compared to the concentration in its prey ($BMF = C_{predator}/C_{prey}$). The BMF should ideally be based on measured data. However, as the availability of such data is limited, the European Committees' guidance document on risk assessment (EU-TGD) [7] provides default values. The resulting maximum BMF from fish to top predators is 100. CSTE [8] notes that these default values are underestimating the biomagnification for (top) predators and that cite studies found body burdens to increase 10-100 from fish to seals and 100-1000 from seals to polar bears. The BMF is dependent on the basis on which the concentration is expressed (i.e. fresh weight, dry weight, lipids). The EU-TGD applies concentrations in fish on a wet weight basis and note that the concentrations used to derive and report BMF values should, where possible, be lipid normalised [7].

To incorporate the process of biomagnification in bioaccumulation models, food-web interactions need to be included, or at least the diet composition of the species of interest. Models range from single-compartment, no growth, first-order depuration models to complex assemblages of trophic levels with increased detail within each level [4]. Some of these models focus predominantly on the chemical's properties, although growth dilution and other biological processes may be incorporated [9]. Most single species and food-web models are validated for temperate lakes [10]. The Arctic environment, which is the subject of this study, has very specific and unique conditions. One of the most important of these conditions is the strong seasonal fluctuation. This is reflected in the organism's nutritional status and lipid content. This may in turn strongly influence lipid concentrations and mobility of accumulated substances.

2.2.2 Selection of contaminants

Not all substances have a potential to bioaccumulate. The most important and widely accepted indication of bioaccumulation potential is a high value of the n-octanol/water partition coefficient (log Kow) or the related BCF (Bioconcentration Factor). For example, a BCF trigger value has been introduced in risk assessment [9]. When the estimated BCF value is above 1,000 (related to a log Kow of app. 3) a traditional PEC/PNEC assessment is no longer considered valid. The scientific value of this BCF/log Kow approach has however been questioned and it was advised to consider parameters other than BCF, particularly for covering bioaccumulation from oral exposures [8]. Factors that are known to influence the bioaccumulation potential are:

- Log Kow;
- Adsorption;
- Hydrolysis;
- Degradation;
- Molecular mass (greater than 700 unlikely to accumulate).

Dietary uptake by aquatic organisms is considered significant, only if the substance has low water solubility, high lipid solubility and is slowly metabolised or eliminated by the prey organism. Within Europe, a step-wise approach is recommended to integrate bioaccumulation in an environmental risk assessment [7]. In practice, substances which are bioaccumulative and persistent will be evaluated in this scheme. Transport through the food-chain is determined by the levels of metabolism in the prey-species. For example, PAHs are metabolised by cod and are therefore not likely to be passed onto higher trophic levels (e.g., seals, polarbears). A substance is indicated as potential bioaccumulating when:

- It has a log Kow ≥ 3 ; or
- it is highly adsorptive; or
- it belongs to a class of substances known to have a potential to accumulate in living organisms; or
- there are indications of potential bioaccumulative behaviour from structural features; and
- there is no mitigating property such as hydrolysis (half-life less than 12 hours).

Background contaminants

There are many substances that should be considered when calculating the background risk. Today, the main Persistent Organic Pollutants (POPs) of concern within the Arctic ecosystems are still chlorinated pesticides (e.g. p,p'-o,p'-DDT, hexachlorocyclohexanes (HCH), toxaphene (CTT)) and cyclodiene compounds including chlordanes, industrial chemicals and by-products (e.g. PCB, hexachlorobenzene (HCB)), combustion products (e.g. chlorinated dibenzodioxines/dibenzofuranes (PCDD/F) and polycyclic aromatic hydrocarbons (PAHs)). Lately increased focus has been directed towards metabolites of the parent POPs as well as "new" environmental toxins such as perfluorinated alkylated substances (PFAS), chlorinated naphthalenes (PCN), polychlorinated paraffins (CPs), polybrominated diphenylethers (PBDE), polybrominated biphenyls (PBB), Polyfluorinated dibenzodioxines and furans (PFDD/F), synthetic musk, phosphorous containing flame retardants, etc. Many of these substances have been found to biomagnify [1-4]. When it comes to the selection of substances to include in model, a choice needs to be made based on the relevance and the data-availability of the substances .

Bioaccumulating contaminants from petro-industry activities

Several operational petro-industry activities (besides calamities such as spills) introduce contaminants into the environment. In this report we will focus on substances discharged with produced water which have been characterised in previous studies (e.g., [11]). Of these produced water components, PAHs, alkylated phenols and heavy metals are most likely to bioaccumulate . Some concern goes to deliberately added production chemicals.

Many studies have been performed on the bioaccumulation and effects of PAHs [7-10], aromatic hydrocarbons [12] and (other) organic contaminants [3, 13, 14], resulting in a dataset of internal effect concentrations for these substances. Kinetic parameters (required for bioaccumulation modelling) are available to some extent [13, 15, 16].

(Heavy) metals are also known to bioaccumulate in the Arctic environment [15]. Kinetic parameters are available for metals [17-20]. The general consensus for metals is that they bioconcentrate [22, 23], but (with an exception for organometals such as methylmercury) that these are not expected to biomagnify as most metals are regulated and excreted.

It is to be questioned whether and how production chemicals need to be included in the intended model. These substances need to comply with the Harmonised Mandatory Control Scheme (HMCS) of OSPAR, which means that they have been screened for PBT (Persistence, Bioaccumulation and (eco)Toxicological) properties [16]. As potentially persistent and bioaccumulating substances are generally not allowed, there is no need to include production chemicals in a risk assessment model for bioaccumulative substances

Important factors influencing the actual levels of bioconcentration and biomagnification are bioavailability and metabolism. Bioavailability is especially important for metals (up to 99% of all metals may be present in a form that prevents uptake by organisms), but also for organic substances such as PAH's (black carbon binding). This is, however, not specific for bioaccumulative substances and will therefore get no specific attention in the proposal model development. Metabolism, however, is an important factor to consider as it is a detoxification mechanism present in vertebrate organisms. Metabolism means that the original substance is transformed into (smaller) metabolites, decreasing its levels in the organism. As a result, this substance is not further transferred into the food-chain. For example, PAH's may not be transferred into the food-chain higher than the level of (small) fish.

2.3 From internal concentration to effect

It is generally assumed that most chemicals will lead to an effect once the internal (body burden) concentration exceeds a critical level, referred to as the Critical Body Residue (CBR). This concept is also the basis of the toxicity Dynamic Energy Budget (DEB-TOX) approach [17] and was underlying the original DREAM-model [18].

The CBR can be determined from toxicity tests in which actual body burdens are measured, but can also be estimated from (external) NOEC's or EC₅₀s using Kow, BCF or kinetic models (see also *Figure 1*).

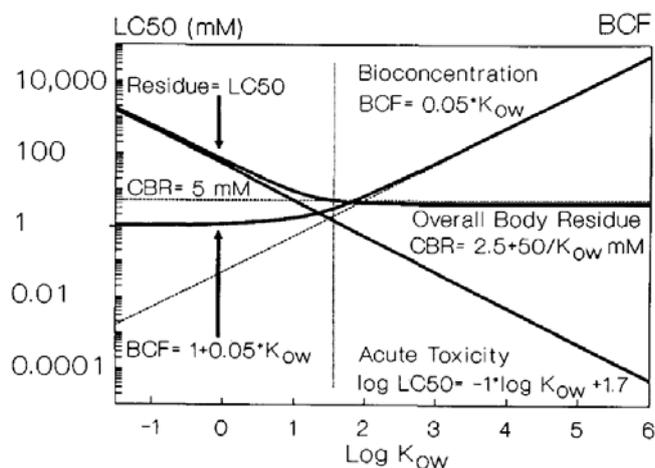


Figure 2 *Idealised relationships between acute toxicity (LC50), bioconcentration (BCF), critical body residue (CBR) and log Kow for small aquatic organisms exposed to narcotic organic chemicals [19].*

Important in the CBR approach is that it is assumed that substances with a comparable mode of action, also have a comparable CBR [9, 20]. This allows for grouping of substances on the basis of their toxic mode of action: polar and non-polar narcosis, unspecified reactivity and specific action [10].

The concept of CBR appears promising but several questions need an answer before it can be used in the risk assessment of substances. The main gaps for the use of CBR were summarised as [9]:

- the need for research to establish threshold tissue concentrations;
- the need to expose a range of taxa to ensure that sensitive species are included;
- data requirements to handle proportionality issues between whole-body and target organ concentrations.

Clearly, the availability of data (or lack thereof) is considered a potential bottleneck in this approach.

The ERED (Environmental Residue-Effects Database, <http://el.ercd.usace.army.mil/ered/Index.cfm>) has been accessed to check the availability of internal effect concentrations for produced water components (*Table 1*). Data is available for most of the components. However, these data are not standardised, i.e. concentrations are measured in different tissues with different effects (endpoints) under various conditions. Specific consideration should thus be taken when using these concentrations for the derivation of effect endpoints for effect and risk assessment. Data for bioaccumulative substances that are traditionally known to be present in the Arctic, but not related to the oil and gas industry, are readily available. For example, the ERED contains 956 results for PCBs based on 122 studies and 87 different species. Polybrominated diphenyl ethers result in 34 hits in the ERED from 5 studies of 5 species. “New” POPs are less available in the database, PFOS for instance could not be found with the initial screening of the database.

Table 1 *Internal effect data availability of produced water components in ERED, the Environmental Residue Effects Database (Source: ERED Website <http://el.erd.usace.army.mil/ered/Index.cfm>, accessed on September 18, 2008)*

Group No.	Representative substance	Number of results	Studies	Species	Effects	Endpoints
1	Benzene	6	5	3 (2 fish, 1 algae)	4	3
2	Naphthalene	20	10	9 (fish, crustacean, bird, bivalve)	7	9
3	Phenanthrene	63	13	8 (fish, crustacean, polychaete, bivalve)	9	20
4	Benz(a)pyrene	189	27	18 (fish, crustacean, bivalves)	9	62
5	Phenol	41	8	3 (fish, echinodermata)	5	19
6	Pentylphenol	n.a.				
7	Nonylphenol	41	4	4 (fish, crustacean)	4	4
8	Octane	2	2	2 (fish, bivalve)	2	2
9	Cu / Mg	1167 / 393	107 / 59	81 / 55	11 / 11	188 / 44
10	Organic acids	n.a.				
11-1n	Exploration and production chemicals	n.a.				

n.a. = not available (i.e. not present in database or no representative substance available)

2.4 From effects to environmental risk

The generic definition of risk used for offshore oil and gas activities is “the probability that biota is adversely affected”. This determined by the exposure level of the contaminant and (a probabilistic distribution of) the sensitivity of the ecosystem to that contaminant. Because species are not exposed to bioaccumulating substances directly from the water column, risk should be determined by comparing internal body burdens for those substances with ecosystem sensitivity, based on a distribution of Critical Body Residues (CBR’s).

Risk assessment of any pressure on the environment is preferably following a tiered approach. The first tier often referred to as PEC:PNEC, is an assessment based on worst case point estimates for exposure (PEC) and ecosystem sensitivity (PNEC). It is often regarded as a screening tool, providing guidance for the focus of the second tier assessment. This second tier is based on probabilistic risk assessment where, preferably, both the PEC and PNEC point estimates have been replaced by probability distributions of realistic exposure and effect concentrations. As a result of this second tier, species - or groups of species – can be identified that are particularly affected by the expected exposure to the pressure. In the third tier, population model for the specific species at risk, or key/indicator species might be used to predict/estimate the consequences for actual populations of these species.

In the following paragraphs we will elaborate on the specific aspects of the three-tier risk assessment with respect to bioaccumulative substances.

Tier1: PEC:PNEC

The obvious analogy to PEC:PNEC in a risk assessment based on internal concentrations seems to be Body Burden: Critical Body Residue. There is however an important difference as the PNEC is an ecosystem toxicity threshold, while the CBR is a species specific toxicity threshold, comparable to a NOEC. But where ecosystem sensitivity in traditional risk assessment can be represented by the lowest available NOEC (with or without a correction factor), this is not the case in risk assessment based on tissue concentrations. Here, the most sensitive elements of the ecosystem is based on a combination if uptake kinetics and the level of the CBR. Because of this combination, the species with the lowest CBR is not necessarily the most sensitive species. An accumulation model¹ is needed to determine the species that is affected at the lowest (external) exposure concentration. Although this seems to be a complicated task, simple bioaccumulation factors (BCF, BAF or BMF) may suffice.

If substances are grouped according to their toxic mode of action, the assessment can be carried out for each group. However, since substances within one group may differ in accumulation characteristics, body tissue concentrations need still to be estimated on a substance-by-substance basis.

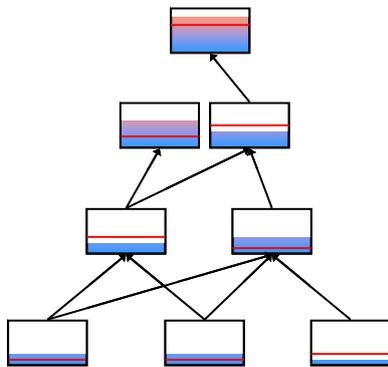


Figure 3 *A theoretical food-web as an example. Boxes indicate species in the food-web, where arrows indicate the diet. Where blue areas indicate internal concentration, and red lines indicate Critical Body Residues.*

Tier 2 Probabilistic Risk Assessment

The essence of probabilistic risk assessment is that the sensitivity of the ecosystem is not longer represented by a single worst case value, but that the variation in sensitivity among all (relevant) species in the ecosystem is included. For external effect concentrations this is done by generating a probability distribution of effect concentrations for a range of species (SSD : Species Sensitivity Distribution)

A complete SSD could be generated from internal effect concentrations (CBR's), as shown in figure 5. Unlike traditional SSD's, an SSD on internal concentrations cannot be used to calculate a fraction of affected species related to an external environmental concentration. As described for the tier 1 approach, a bioaccumulation model (either a full kinetic model or simple bioaccumulation factors), can be used to estimate the external concentration that would lead to the CBR in a specific organism. In this way a SSD can be generated that can be used to calculate the potentially affected fraction of a species (PAF) in relation to ambient environmental concentrations.

¹ This should be a static model, or a dynamic model used to calculate equilibrium.

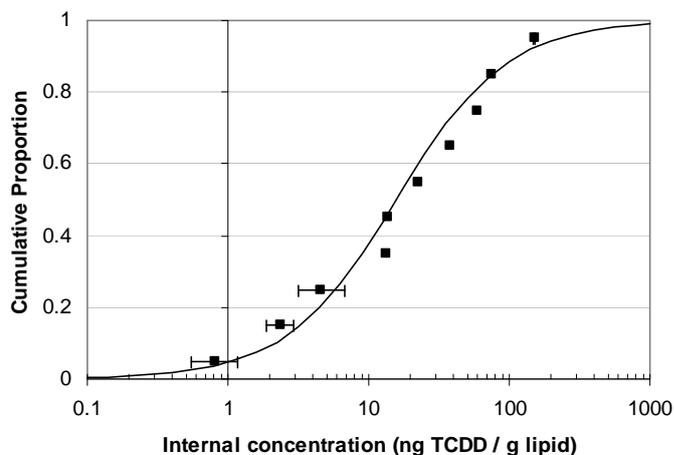


Figure 4 *An example of a Species Sensitivity Distribution based on internal concentrations of TCDD based on data from Steevens et al. [21]. Note that there is no direct link with external concentrations in the environment.*

It must be noted that it is not essential to make this translation to external concentration, as the fraction of affected species could also be directly generated from the accumulation model. However, an SSD translated to external concentration would significantly reduce the required computational resources.

Tier 3: Population Dynamics

This final tier could be relevant to study in more detail the effects on species identified as key or indicator species. Such an approach could include the actual geographic distribution of species, as well as specific population dynamics such as growth, reproduction, survival and length of specific life stages. Many approaches would be possible, determined by the actual species under study. As such, this tier will not be considered relevant for the development of a (generic) risk assessment model for bioaccumulative species.

EIFs are based on the second tier risk assessment, making use of the species sensitivity distributions. Using the approach mentioned under tier 2, comparable SSD's can be used representing the effects of (food-chain-) accumulation. This effectively means that for bioaccumulative substances (background contamination and/or produced water components a potentially affected fraction (per substance : PAF, or for all identified substances: ms PAF) can be calculated. The EIF could represent the water volume in which the msPAF exceeds 5% (i.e., the water volume in which concentrations are such that more than 5 % of the species are potentially affected due to bioconcentration or biomagnification of bioaccumulative substances).

3 Proposed modelling concept

3.1 From exposure to internal concentrations

Based on considerations in the previous chapter, we propose to calculate internal concentrations with a kinetic model. A simple, tiered approach (in line with Alonso, [22]) containing a simple food-web is expected to be a good starting point. More advanced models such as described by Traas et al. [14] and Hendriks et al. [2, 3, 23], will provide useful elements for further development of the model. Currently, a bioaccumulation model focussing on the Barents Sea is under development at the Dutch Institute of Ecology Research. The use of this model will be considered in this specific area [24].

A relatively simple food-web is expected to suffice. As PAH's (most likely the most accumulative component of the produced water stream) are metabolised in fish and therefore not transported further into the food chain, cod is expected to represent the highest relevant trophic level in the food web.

It is not sure whether sufficient data is available to simulate seasonal variations. In that case a worst case approach might be followed by choosing the most sensitive period from the yearly cycle.

Finally, it must be mentioned that for some substances internal concentrations need not to be modelled, but derived directly from actual measurement of concentrations in body tissues. This is likely to be the case for background contamination that is present in extremely low concentrations, but found in biota at significant levels.

3.2 From internal concentration to effect

For bioaccumulating substances, the Critical Body Residue is considered a useful element to be used in risk assessment of those substances. The CBR is related to the specific Toxic Mode of Action (TMOA) of a substance [19, 25]. All substances (discharged or present as background contamination) therefore need to be grouped according to their TMOA. It is important to consider the target site for which an effect level is reported. If the CBR is expressed as the concentration in liver tissue, then one must be aware that the exposure modelling (i.e., bioaccumulation modelling) includes the liver as a specific compartment. Therefore, harmonisation of CBRs is an important task.

Some databases are available containing CBR data. As there are no standardised protocols for deriving CBR's, data from databases and literature need to be checked for their quality on a case-by-case basis. It is further expected that for a number of species and Toxic Modes of Action no suitable data is available. Several techniques are available and will be applied to generate effect data, like interspecies correlation estimates [26] or the use of surrogate species. Finally, for all combinations of substances and species the metabolic routes will be studied using literature. If toxic metabolites are formed, these need to be included in the model.

3.3 From effects to environmental risk

We propose to follow a tiered approach for risk assessment, in which the first tier is based on a worst case ecosystem toxicity threshold and the second tier is based on species sensitivity distribution. The third tier, usually based on species specific (population) modelling, is not included in the scope of the proposed project.

In both tiers, the (static) food-chain accumulation model will be used to find the external seawater concentration that would lead to internal tissue concentrations equal to the CBR. In the first tier, the objective is to identify the species in which the CBR is exceeded at the lowest ambient concentration (i.e., the most sensitive species). This external concentration, eventually with an additional assessment factor, can be considered comparable to the PNEC. For the second tier risk assessment, the CBR of each species in the food-web will be translated into external seawater concentrations (using the same food-chain accumulation model) in order to construct a SSD based on external concentrations instead of CBR's.

The PNEC and SSD can subsequently be used in a way comparable to the traditional risk assessment as currently performed for the EIF.

Finally, we propose to evaluate the feasibility of:

- replacing the food-chain accumulation model by relatively simple bioconcentration factors, such as BCF, BAF and BMF.
- replacing a substance based approach by an approach based on the Toxic Mode of Action.

3.4 Application in 2 case studies

The developed model will be applied in 2 case studies, each case study with specific requirements allowing testing and demonstrating the bandwidth of the applicability of the risk assessment model.

The case studies will focus on:

- the arctic region, giving specific attention to bioaccumulative substances that concentrate in the polar areas. In order to be able to evaluate the impact of offshore oil and gas activities (drilling, production) it is essential to know the 'background risk' of contaminants already present in the region. The proposed methodology will enable us to calculate the background risk expressed as fraction of potentially affected species in the region;
- the Norwegian sea, focusing on the risk of produced water discharges, taking account of the potential bioaccumulative behaviour of some of the components. The case study will demonstrate the discriminative power of the model, allowing for elimination of the currently used weighing factors for persistent, bioaccumulative substances. The proposed methodology will enable us to calculate the volume of water around the discharge point where the potentially affected fraction of species exceeds 5% as a result of the discharge of bioaccumulative substances.

4 Outline of a research project for model development

In this chapter we provide the outlines of a research project that would lead to the development of a risk assessment model for bioaccumulative substances that is compatible with the current EIF approach, but can also be used in more advanced impact assessment studies.

We have distinguished a series of work packages, each of which will be briefly described. Main tasks within each packages are identified. In the second paragraph of this chapter we have provided an estimation of the required resources for this project.

4.1 Work packages

Below the work content for developing the proposed model is presented. Each work package focuses on the scientific contents, but also implies management and reporting. This has not specifically been addressed.

WPI. From exposure to internal concentrations

This work package comprises the development of an (Arctic) food-web accumulation model that is capable of modelling body tissue concentrations in all relevant trophic levels for (a selection of) bioaccumulative substances present in the ambient environment. The same model must also be capable of translating critical body burdens into the related external effect concentrations.

Task 1.1. Definition of the food-web

- Use food-web model of DeLaender is a basis [24]
- Define trophic levels need to be included
- Define species need to be included
- Determine minimal complexity required
- Inventory of relevant species data (diets, etc.)

Task 1.2. Development of the bioaccumulation model

- Definition of the required complexity
- Development of the basic model, based on Alonso
- Extension of the basic model by inclusion of elements from Hendriks (OMEGA) [2, 3, 23] and Traas [14] (for effects assessment)
 - o Note: dependent on the required complexity, it might be useful to use the OMEGA model as a starting point.

Task 1.3. Preparation of substance profiles (fate)

- Selection of relevant substances (at least containing PAHs, alkylated phenols, PCB's and halogenated flame retardants)
- Inventory of existing exposure data (water concentrations, body tissue concentrations)
- Inventory of existing accumulation factors (BCF, BAF, BMF)
- Inventory of parameters relevant for accumulation kinetics (minimally required log Kow, others may be useful)

Task 1.4. Demonstration and validation of the model

- Estimation of body tissue concentrations using the food-chain accumulation model
- Comparison with data on observed body burden concentrations

Task 1.5. Experimental data generation to fill critical data gaps (optional)

- Chemical analysis of body tissues to determine actual body tissue concentrations of the selected substances in various species
- Bioconcentration / bioaccumulation experiments to determine uptake kinetics and/or bioconcentration factors.

WP2. From internal concentrations to effect

In this work packages the focus will be on an elaboration of the Critical Body Residue, and the collection of relevant information related to the Toxic Mode of Action (TMoA) of the selected substances.

Task 2.1 Inventory of CBR data

- Extensive literature review to collect all available data related to the CBR for the selected substances (task 1.3) in the species relevant for the defined food-web (task 1.1). The ERED database will be used as a starting point
- Definition of a series of quality criteria to be applied to the CBR data.
- Update of the substance profiles with qualified CBR data, relevant for the species under study

Task 2.2. Elaboration on the Toxic Mode of Action (TMoA)

- Literature review on the use of TMoA
- Determination of the TMoA of each selected substance in order to group the substances
- Determination of the CBR for each TmoA-group
- Evaluation of the feasibility of using TMoA as a basis for risk assessment of bioaccumulative substances

Task 2.3. Experimental data generation to fill critical data gaps (optional)

- Dedicated experiments with species from different trophic levels in order to determine the Critical Body Residue for specific substances (or groups of substances based on the TMoA)

WP3. From effects to environmental risk

This work package comprises the development of the risk assessment model based on CBR and food-chain accumulation modelling.

Task 3.1. Development of tier 1 risk assessment (deterministic)

- Estimation of ecosystem threshold values based on CBR and reversed bioaccumulation modelling (using the kinetic model)
- Idem, using bioconcentration factors (BCF, BAF, BMF)
- Comparison of the feasibility of using either kinetic modelling or simple bioconcentration factors
- Demonstration of the principle using a real-world case study

Task 3.2. Development of tier 2 risk assessment (probabilistic approach)

- Derivation of SSD curves based on CBR data and reversed bioaccumulation modelling (using either the kinetic model or bioconcentration factors, depending on the outcome of the evaluation in task 3.1)
- Demonstration of the principle using a real world case study

Task 3.3 Development of tier 3 risk assessment (population modelling)

- Not in the scope of the current project.

Task 3.4. Integration of (tier 2) RA of bioaccumulative substances in the EIF concept

- Translation of msPAF into EIF values for produced water components and background concentrations
- Combination of the EIF values of bioaccumulative substances with 'traditional' EIF values
- Demonstration of the principle using a real-world case study

WP4. Uncertainty analysis

As the inclusion of bioaccumulation in the concept of generating EIF values is making the risk assessment approach much more complex, it is also likely to increase the uncertainty in the models' results.

Task 4.1. Sensitivity analysis

- Running the model with subsequent changes (e.g., + or – 10%) in its parameter values
- Identification of the most sensitive parameters

Task 4.2. Uncertainty analysis

- Determination of the range of possible values for the identified sensitive parameters, preferably summarized in a statistical distribution
- Monte Carlo simulation with the model using the uncertainty ranges on the most sensitive parameters
- Determination of the uncertainty in the final model results based on the outcome of the Monte Carlo Simulation

Task 4.3. Implications for the models' results

- Demonstration of a real-world case with inclusion of the uncertainty ranges
- Conclusion on the implication of the model uncertainty
- Recommendations for decreasing the model uncertainty (if deemed necessary)

Task 4.4. Gathering or generating data to decrease the model uncertainty (optional)

- Literature review
- Experimental studies

WP5. Scientific publication

This project is expected to lead to three scientific publications:

- Food-chain accumulation modelling
- CBR and risk modelling
- Demonstration with the real-life case

4.2 Indicative Workload and Budgets

Overall workload, budget estimates and planning

Work content: 345 days

Meetings: 24 days (6 meetings, 2 persons, 2 days)

Travelling and housing: 9000 Euro, 1500 Euro per meeting.

Overall budget (excluding optional tasks for –experimental- data generation): 395 kEuro excluding VAT, based on 66% 2009 and 34% 2010 (see planning below). Budget estimates for both years –based on relevant wages– are, respectively, 260 and 135 kEuro (or app. 2.3 and 1.2 MNok).

In this budget subcontracting of Hendriks and Delaender is included for bioaccumulation and food-chain modelling.

Proposed project planning:

	2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<u>WP1. From exposure to internal concentrations</u>								
<u>WP2. From internal concentrations to effect</u>								
<u>WP3. From effects to environmental risk</u>								
<u>WP4. Uncertainty analysis</u>								
<u>WP5. Scientific publication</u>		---	---	---	---			

Workload breakdown per work package

WP1. From exposure to internal concentrations

90 days

Contributions by deLeander and Hendriks foreseen
pm for eventual data generation

WP2. From internal concentrations to effect

65 days

pm for eventual data generation

WP3. From effects to environmental risk

85 days

WP4. Uncertainty analysis

65 days

Contributions by deLaender and Hendriks foreseen
pm for eventual data generation

WP5. Scientific publication

40 days

Contributions for Frederik and Jan (app 30%)

Workload breakdown per task

WP1. From exposure to internal concentrations

Task 1.1. Definition of the food-web

- 25 days

Task 1.2. Development of the bioaccumulation model

- 30 days

Task 1.3. Preparation of substance profiles (fate)

- 20 days

Task 1.4. Demonstration and validation of the model

- 15 days

Task 1.5. Experimental data generation to fill critical data gaps (optional)

- pm

WP2. From internal concentrations to effect

Task 2.1 Inventory of CBR data

- 40 days

Task 2.2. Elaboration on the Toxic Mode of Action (TMoA)

- 25 days

Task 2.3. Experimental data generation to fill critical data gaps (optional)

-

WP3. From effects to environmental risk

Task 3.1. Development of tier 1 risk assessment (deterministic)

- 40 days

Task 3.2. Development of tier 2 risk assessment (probabilistic approach)

- 25 days

Task 3.3 Development of tier 3 risk assessment (population modelling)

- pm

Task 3.4. Integration of (tier 2) RA of bioaccumulative substances in the EIF concept

- 20 days

WP4. Uncertainty analysis

Task 4.1. Sensitivity analysis

- 20 days

Task 4.2. Uncertainty analysis

- 30 days

Task 4.3. Implications for the models' results

- 15 days

Task 4.4. Gathering or generating data to decrease the model uncertainty (optional)

- pm

WP5. Scientific publication

- 40 days

5 Quality Assurance

IMARES utilises an ISO 9001:2000 certified quality management system (certificate number: 08602-2004-AQ-ROT-RvA). This certificate is valid until 15 December 2009. The organisation has been certified since 27 February 2001. The certification was issued by DNV Certification B.V. The last certification inspection was held the 16-22 of May 2007. Furthermore, the chemical laboratory of the Environmental Division has NEN-AND-ISO/IEC 17025:2000 accreditation for test laboratories with number L097. This accreditation is valid until 27 March 2009 and was first issued on 27 March 1997. Accreditation was granted by the Council for Accreditation, with the last inspection being held on the 12th of June 2007.

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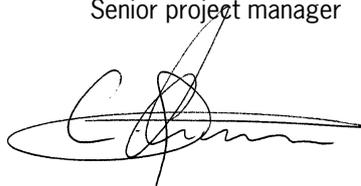
7 Justification

Rapport C109b/09
Project Number: 75003.06

The scientific quality of this report has been peer reviewed by the a colleague scientist and the head of the department of Wageningen IMARES.

Approved: C.C. Karman
Senior project manager

Signature:



Date: 15 October 2009



Approved: Drs. J.H.M. Schobben
Department head Environment

Signature:

Date: 15 October 2009

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